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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,955	06/19/2002	Dominique Bonnet	1217-0156P	2612
2292 7590 02/01/2008 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			EXAMINER AUDET, MAURY A	
			ART UNIT 1654	PAPER NUMBER
			NOTIFICATION DATE 02/01/2008	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

# Office Action Summary

Application No.

10/049,955

Applicant(s)

BONNET ET AL.

Examiner

MAURY AUDET

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 8/2/07.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 21-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 8, 9 and 21-23 is/are rejected.
- 7) ☒ Claim(s) 2-7, 10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

Art Unit: 1654

### DETAILED ACTION

The present application has been transferred from former Examiner Khanna to the present Examiner.

Applicant's amendment and response of 8/2/07 are acknowledged. Due to the amendment of the claims, the subject matter necessitated an updated search for which the present art of record is now applied.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Cohen et al. (US 6,232,456 B1).

Art Unit: 1654

Cohen et al. teach a coupling process between a peptide (antibody; anti-FLAG M2 monoclonal antibody) and a non-peptide (namely, agarose which comprises galactose, having alcohol (-OH) functional groups therein), by a link (manufactured by Eastman Kodak Co., New Haven, Conn.). Cohen et al. also teach that it was well known that peptides are purified via HPLC (all in col. 54, lines 21-36).

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen et al. (US 6,232,456 B1) in view of Bolognesi et al. (US 5,464,933).

Cohen et al. is discussed above. Cohen et al. does not expressly teach a coupling process wherein peptide (e.g. antibodies) may be bound to other non-peptide compounds using the same hydrazide link.

Art Unit: 1654

Bolognesi et al. teach that other non-peptide compounds, such as lipid fatty acids, may be bound to peptides at the N or C terminus. And that even internally, peptides may be modified to use hydrazide as the link, between amino acid residues (col. 10, lines 6-45).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to link another non-peptide compound such as a lipid fatty acid to a peptide via a hydrazide bond, in Cohen et al., because Bolognesi et al. teach that other non-peptide compounds such as lipid fatty acids may be covalently bound via any known linkage to peptides at the C or N terminus. Based on the combination of Bolognesi et al. and Cohen et al., using hydrazide to link peptides internally or externally (e.g. to non-peptides) was well known in the art. Thus, it would have been merely routine optimization to link the lipid fatty acid of Bolognesi et al. to the peptide of Cohen et al., using the same hydrazide link which Cohen used to another non-peptide compound (saccharide, galactose).

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen et al. (US 6,232,456 B1) in view of Kuhajda et al. (US 5,665,874).

Art Unit: 1654

Cohen et al. is discussed above. Cohen et al. teach that it is well known to purify peptides generally by HPLC, but does not expressly teach use of HPLC purification to arrive at the antibody of the antibody-hydrazine-non-peptide conjugate (claims 21-23).

Kuhajda et al. is cited merely by example to teach that HPLC purification is used to arrive at antibodies was well known in the art, namely that "[t]o purify the antibody a . . . SELECTISPHER-10 activated tressyl column HPLC affinity column (Pierce Chemical Co.) was derivatized with the Hpr synthetic peptide."

If not inherent in the Eastman-Kodak process, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use HPLC purification to arrive at the peptide antibody of the peptide-hydrazine-non-peptide conjugate taught in Cohen et al., based on the advantageous teachings of Bolognesi et al. that the use of HPLC purification to arrive at peptide antibodies was well known in the art.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### ***Claim Objections***

Claims 2-7 and 10 are objected to as being dependent upon rejected base claim. Were independent claim 1, amended to include all the limitations of the dependent claims thereto, the

Art Unit: 1654

claims would likely receive favorable consideration. The primary and secondary references were not found to reasonably teach or render obvious the limitations of these claims.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

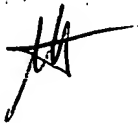
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1654

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



CHRISTOPHER R. TATE  
PRIMARY EXAMINER